K022121

JUL 2 9 2002

SECTION 2 - 510(K) SUMMARY

Name and Address of Applicant
Nihon Kohden America, Inc.
Attn: Regulatory Affairs
90 Icon Street
Foothill Ranch, California 92610
Phone: (949) 580-1555
Fax: (949) 580-1550

Device Name and Classification: PSG amplifier and accessories. The device classification is unchanged. The device is classified by the Neurology Panel under 21 CFR Part 882.1400 "Electroencephalograph" per GWQ. Common names for the device include Electroencephalograph (EEG) and Polysomnograph (PSG).

Legally Marketed Predicate: Nihon Kohden EEG 9100, cleared under 510K, K011204

There are no significant changes in function, biocompatibility, performance or manufacturability compared to the predicate device that would affect the safety and effectiveness of the device as intended for use. Therefore, Nihon Kohden believes that the new PSG amplifier is substantially equivalent to the predicate EEG device. The device has the same intended use and indications for use as the existing marketed device and uses the same fundamental scientific technology.

Description and Intended Use: The device is intended to record the physiological data required for EEG and sleep studies (Polysomnography or PSG). These data, may be used by clinicians in Sleep Disorders, Epilepsies and other disorders as a diagnostic aid. This device is intended for use by medical personnel and will be available for use within a medical facility or outside of a medical facility under direct supervision of a medical professional on all patient populations.

Performance Testing

- The device complies with IEC 601-1 sub-clause 56.3(c) implemented by 21 CFR Part 898 Performance Standard for Electrode Lead Wires and Patient Cables. To date, no other special controls or performance standards are known or established for this device. The device is designed to comply with the following voluntary industrial standards: IEC 60601-1 (1988-12), Amendment 1 (1991-11), Amendment 2 (1995-03), IEC 60601-1-1 (1992-06), Amendment 1 (1995-10), IEC 60601-1-2 (1993-05), CISPR11 Group 1, Class B, IEC 60601-2-26 (1994)

- The PSG unit is not sterile.

- The device does not directly contact patients. Accessories that contact patients, such as the EEG electrodes and SP02 probes are the same as current available component materials and accessories legally cleared and marketed in the USA (see accessories list). *Therefore, good laboratory practice studies were not required per 21 CFR, part 58.*

- The device was developed in accordance with design controls and operation of the device was appropriately verified and validated using test methods as with all other existing devices. The device was subjected to environmental testing including temperature/humidity stress testing, electromagnetic interference / electromagnetic compatibility testing and safety standards testing

and performance testing procedures. Test criteria are established prior to testing based upon product specifications and applicable standards. The completed testing showed that the device met its product specifications and verified conformance to safety, reliability, and applicable standards. Software verification and validation tested the operation of the software functions of the device. The results confirmed that the device performed within specifications (see Attachment # 6).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 9 2002

Ms. Serrah Namini
Regulatory Affairs Manager
Nihon Kohden America, Inc.
90 Icon Street
Foothill Ranch, California 92610

Re: K022121
Trade/Device Name: PSG Input Box, Model JE-912AK
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: GWQ
Dated: June 28, 2002
Received: July 1, 2002

Dear Ms. Namini:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

G. Indications for Use Statement

510(k) Number (if known): K022121

Device Name: PSG input Box

Indications for Use:

The device is intended to record cerebral, extracerebral and other bio-potential activities for EEG and Sleep Studies via legally marketed PSG reading software. These data may be used by clinicians in sleep disorders, Epilepsies and other related disorders as a diagnostic aid.

The device is intended for use by medical personnel in any location within a medical facility, physician's office, laboratory, clinic or nursing home or outside of a medical facility under direct supervision of a medical professional. The device will be available on all patient populations (including adults and children) as determined by a trained professional.

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022121